

Non Provisional Patent Application of
Alvin Needleman and Harriet Needleman
For

TITLE: DIETARY SUPPLEMENT FOR SUPPRESSING APPETITE, ENHANCING AND
EXTENDING SATIETY, IMPROVING GLYCEMIC CONTROL AND STIMULANT FREE

CROSS-REFERENCE TO RELATED APPLICATIONS Not Applicable

FEDERALLY SPONSORED RESEARCH Not Applicable

SEQUENCE LISTING OR PROGRAM Not Applicable

BACKGROUND OF THE INVENTION—FIELD OF THE INVENTION

This invention relates to a method for promoting appetite suppression and enhancing satiety by elevating neurotransmitter levels, decreasing local fat absorption and stimulating glycemic control without promoting anxiety.

References Cited [Referenced By]		
U.S. Patent Documents		
6503543	Jan., 2003	Hudson
4650789	Mar., 1987	Pollack
6436899	Aug., 2002	Portman
6277396	Aug., 2001	Dente
6025363	Feb., 2000	Giles
5602164	Feb., 1997	Shinitzky et al.
4393049	Jul., 1983	Horrobin
5900240	May, 1999	Tomer et al.

ABSTRACT

The invention considers the failures of most weight management and appetite control products and projects. The invention combines three levels of formula activity to cancel rebound weight gain and promote long-term success. The invention does not use thermogenic agents, stimulants, catalytic compounds or anabolic ingredients. The first level of formula activity enhances and prolongs post meal satiety, decreasing appetite by 16% to 35%. The second level of formula activity stimulates carbohydrate metabolism, reduces blood glucose levels, slows gastric emptying time and increases insulin availability beyond Energy Homeostatic minimums. Thereby, affecting appetite control and reducing weight gain bias. The third level of formula activity binds lipids and bile acids, slows gastric emptying time and inhibits lipogenesis. Cholecystokinin levels are enhanced and Ghrelin, an anti satiety polypeptide, is inhibited. Additionally, elevated neurotransmitter levels (serotonin) stimulated by formula ingredients reduces; anxiety and aggressive behavior, shortens sleep latency and improves mood disorders and depression.

BACKGROUND OF THE INVENTION-PRIOR ART

Sixty percent of the population of the United States is overweight. The trend toward larger portion sizes, in and out of the home, is increasing rather than decreasing. Attempts by existing weight management supplements to reverse weight gain have met with little success. Current weight management and appetite suppression supplement combinations follow repetitive historical rational and unfounded biochemical hypothesis, relying more on over aggressive marketing than fact.

Dietary supplement formulas containing a thermogenic substance or combinations of thermogenic substances. Thermogenic ingredients were chosen from a group consisting of caffeine, catechins, Ma Huang, ephedrine, synephrine, norephedrine and psuedoephedrine. The formulas often-added White willow bark, a salicylate and precursor of acetyl salicylic acid (aspirin) the rational being the synergistic (multiplier) effect of the salicylate on the thermogenic ingredients in the formula. Thermogenic products cause serious side effects including depletion of adrenal keto-steroids, anxiety, irregular heart rates, drug incompatibilities and exacerbation of high blood pressure.

A second group of dietary supplement formulas sought to reduce appetite by introducing bulk generating combinations of soluble and insoluble fibers. Formulas containing single or combinations of the dietary fiber group guar gum, pectin, acacia gum, beta-glucan, fruit fibers, vegetable fibers, legume fibers, plantago, psyllium, xanthan, agar, alginic acid, cellulose gum, methylcellulose, agarose, dextran, tragacanth, karaya, glucomannan, locust bean, konnyaku mannan and carrageenan. Unfortunately, very little weight loss or appetite control was achieved using high fiber products other than the discomfort associated with increased flatulence, gastric reflux and indigestion. A method to relieve the uncomfortable flatulence side effect is proposed by U.S. patent 5773427 to Charles E. Day (1996) for the inclusion of an amount of chitosan marine fiber in a specific ratio to formula fiber.

A third group of weight management products introduces natural herbal formulas, natural ingredients used alone, combined with vitamins and minerals and in formula with soluble and insoluble fibers. The most popular natural ingredient in current use is *Garcinia cambogia* (Hydroxycitric Acid), an exotic fruit grown in South India, often combined with chitosan, a deacylated marine fiber and chromium picolinate. The formula rational is based on the ability of *Garcinia cambogia* to competitively inhibit the extramitochondrial enzyme adenosine triphosphate-citrate. As a citrate cleavage enzyme that may play an essential role in de novo lipogenesis inhibition, *Garcinia cambogia* is claimed to lower body weight and reduce fat mass in humans. In a 1998, study 135 subjects were randomized to either active hydroxycitric acid (*G.cambogia*) or a placebo for twelve weeks the results were published in JAMA 1998;280:1596-1600. “*Garcinia cambogia* failed to produce significant weight loss and fat mass loss beyond that observed with the placebo”.

Various chemical approaches have been proposed for controlling obesity. Anorectic agents, such as dextroamphetamine, are associated with undesired side effects. Indigestible materials such as mineral oil or neopentyl esters (see U.S. Pat. No. 2,962,419) have been proposed as substitutes for dietary fat. Diethylaminoethyl dextran, an ion exchange material, has been indicated to inhibit fat absorption in the body. Fischetti, Offenlegungsschrift 2,655,199, Chem. Abstr. 87:112005 h (1977). *Garcinia* acid and derivatives have been described as treating obesity by interfering with fatty acid synthesis. Swell able cross-linked vinyl pyridine resins have been described as appetite suppressants via the mechanism of providing non-nutritive bulk, U.S. Pat. No. 2,923,662. Cationic polymers such as dialkylaminoimides of alene/maleic anhydride copolymers have been described as inhibiting pancreatic lipase, U.S. Pat No. 4,211,765.

None of the previous methods is entirely satisfactory. Controlled diet and controlled appetite remains the most prevalent technique for controlling obesity, with surgical techniques such as temporary ileal bypass surgery, being employed in extreme cases. It would be desirable to provide a new means for controlling weight gain, maintaining ideal body mass, controlling fat absorption and maintaining ideal blood glucose levels by regulating carbohydrate metabolism.

BACKGROUND OF THE INVENTION-OBJECTS AND ADVANTAGES

Various methods have been proposed for weight control to combat obesity. One of the more common methods is the use of relatively low-fat diets containing less fat than a normal diet, although some fat is generally present even in diets considered relatively "fat Free". Fats are solids or liquids oils generally consisting of glycerol esters with higher fatty acids. Dietary sources of fats include both animal and vegetable fats, including predominantly triglyceride esters of both saturated and unsaturated fatty acids, as well as some free fatty acids. Glyceryl tristearate, glyceryl tripalmitate and glyceryl trioleate are among the common esters.

Maintenance of fat-free or low-fat diets is difficult. The presence of fats in a great many food sources greatly limits the food sources, which can be used. Additionally, fats contribute to flavor, appearance and physical characteristics of many foodstuffs. Such factors adversely affect the acceptability of low-fat diets, and make the maintenance of such diets difficult.

This invention does not contain a thermogenic substance or a catalytic element such as white willow bark, a salicylate-containing compound, used to multiply the effect of the thermogenic ingredients to accelerate metabolism. By providing a stimulant, free supplement serious side effects are avoided as appetite is suppressed and glycolysis controlled.

This invention does not use large quantities of soluble or insoluble fiber or combinations of fibers to produce a mechanical sensation of fullness. Studies show a degree of discomfort and bloating by the user but do not show a reliable pattern of success using this approach. This invention uses an acetylated marine fiber with saponin enhanced fat absorption and slowed gastric emptying time, reducing the amount of local fat absorbed and leaving the user with a comfortable sensation of gastric satisfaction.

This invention does not use natural herbal combinations without sufficient clinical or outcome studies to provide reliable evidence of positive repeatable results. The natural products used in this invention

have a history of successful performance and authenticated evidence of each ingredient's participation in the performance results of this invention. Individual ingredient clinical and biochemical validity will be identified under “claims”.

The chemical agents and controlled and dangerous drugs proposed for controlling obesity are primarily the purview of the pharmaceutical industry and therefore their distribution is confined to prescription use. Historically, chemical agents have not provided more than a 5% reduction in weight, while contributing to unwanted side effects.

This invention approaches its objectives biochemically formulating active ingredient groups, which stimulate a series of physiological events: (1) decreased local fat absorption and slowed gastric emptying time. (2) Maintenance of ideal blood glucose levels through regulated carbohydrate metabolism. (3) Enhanced and extended satiety by elevating serotonin levels. (4) Ameliorating the effects of reduced serotonin levels, improving sleep and reducing anxiety and stress. (5) Taken twice daily, immediately following meals, the invention reduces food intake by 16% to 35% in three days (results may vary between individuals).

SUMMARY

The invention, “Dietary Supplement for Suppressing Appetite, Enhancing and Extending Satiety, Improving Glycemic Blood Levels and Stimulant Free” achieves a high level of success and consistency from the synergistic relationship between the ingredients, the action groups and the trigger mechanisms in the invention, Comprising; Aloe Freeze Dried Powder 200X, Vitamin B3, Vitamin B6, ingested proteins and carbohydrates.

DETAILS AND DESCRIPTIONS OF THE PREFERRED EMBODIMENTS

The invention is based on three primary mechanisms of action: First, increasing serotonin levels to enhance and prolong satiety, subsequently reducing appetite and food intake by 16% to 35%. Tryptophane is a naturally occurring essential amino acid found in most protein foods, 80% of the circulating tryptophane is bound to plasma albumin with the balance of 20% circulating in the blood as free tryptophane. The invention includes a natural source of tryptophane L-5-hydroxytryptophane from the seeds of the African plant *Griffonia simplicifolia*, present in the range of 60mg to 80mg per serving, to supplement both the bound and the circulating tryptophane. To be effective tryptophane must be

transported across the blood brain barrier to be metabolized into serotonin. (1) Bound tryptophane is released from plasma albumin by salicylic acid or acetyl salicylic acid (Aspirin) in a range of 0.06Gm to 0.3Gm. The formula ingredient "Aloe Freeze Dried Powder 200x" present in the range of 95mg to 120mg per serving contains between 0.009% and 0.014% salicylic acid breaking the tryptophane/plasma albumin bond and increasing the quantity of circulating free tryptophane. (2) Un-bound tryptophane, circulating tryptophane and L-5-Hydroxytryptophane are transported across the blood brain barrier when a carbohydrate source consisting of glucose, maltose, sucrose or any combination thereof is present to facilitate the transport of tryptophane and 5-L-hydroxytryptophane across the blood brain barrier. Additionally, carbohydrate intake with its insulin-releasing action helps to improve the albumin-bound tryptophane/Large electrically neutral amino acids (LNAA) ratio in favor of the tryptophane and increases the amount of tryptophane crossing the blood brain barrier into the brain. Two additional ingredients are provided in the invention to facilitate tryptophane transport into the brain and/or promote its conversion to serotonin, vitamin B3 0.15mg to 20mg per serving and vitamin B6 0.15mg to 20mg per serving. The Blood Brain barrier, in humans is a barrier that exists to allow brain functions to operate in an independent environment separate from the rest of the body to protect the sensitive nature of the Central Nervous System. For the reasons and explanations given, the invention: "The Dietary Supplement For Suppressing Appetite, Enhancing and Extending Satiety, Improving Glycemic Control and Stimulant free" is taken as three tablets with water immediately following a meal (One serving size).

Second, fiber, the absorption of local fat, reduced gastric emptying time and the relationship to satiety and decreased appetite in the invention. Chitosan is a polycationic polymer containing more than 5000 glucosamine units and is obtained by alkaline deacetylation of chitin from shellfish exo-skeletons; chitosan is present in the invention in a range of 300mg to 600mg per serving. Chitosan is a positively charged fiber that chemically binds to negatively charged lipids, fats and bile acids during digestion, thereby reducing fat absorption and slowing gastric emptying time. (ARS Medicina, Helsinki 1994 study showed that test subjects lost 8% of their body weight on chitosan). Dietary supplements that bind lipids aid in weight loss, with the addition of saponins to the invention, in a range of 3mg to 5mg per serving, (contained in the Aloe Freeze Dried Powder 200x) the capacity of chitosan to bind fat is increased. *Garcinia cambogia* (50% hydroxy citric acid) present in the invention in a range of 100mg to 150mg per serving

CLAIMS

What is claimed is: